

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/820,848 Confirmation No. 8673
Applicant : Lawrence V. Tannenbaum
Filed : April 09, 2004

TC/A.U. : 1631
Examiner : LIN, Jerry

Docket No. : CHPPM 03-22 03
Customer No. : 27370

For: METHOD FOR FIELD-BASED ECOLOGICAL RISK ASSESSMENT USING RODENT SPERM ANALYSIS

SUMMARY OF EXAMINER INTERVIEW AND SUPPLEMENTAL REMARKS

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Commissioner for Patents
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Sir:

Applicant thanks Examiner Lin for the courtesies extended to him, Marcus Streips of the U.S. Army Medical Research and Materiel Command, and representative Warren Zitlau at the personal interview on May 29, 2008. The following is a summary of the Examiner Interview and Remarks in response thereto.

I. SUMMARY OF EXAMINER INTERVIEW

The formal matters under 35 U.S.C. 112, second paragraph, and rejections under 35 U.S.C. 103(a) were briefly discussed in light of claim amendments and the Declaration Under 37 C.F.R. 1.131/1.132.

The majority of the interview was spent discussing the rejection of Claims 1, 3, 5-6, 15-16, and 18-23 under 35 U.S.C. 112, first paragraph, as assertedly being non-enabled.

Independent Claim 18 recites determining whether the comparison between sperm count, sperm motility, and sperm morphology of rodents from a contaminated site

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and of the rodents from an animal reference site exceeds sperm parameter benchmarks for sperm count, sperm motility, and sperm morphology, thereby indicating if the rodents from the contaminated site have compromised reproductive success and making a determination about the health of terrestrial site mammals at the contaminated site based on whether said comparison exceeds the sperm parameter benchmarks.

Independent Claim 22 recites determining whether the comparison between sperm count, sperm motility, and sperm morphology of rodents from a contaminated site and of the rodents from a reference site exceeds one or more sperm parameter thresholds-for-effect, thereby indicating if the rodents from the contaminated site have compromised reproductive success; and making a determination about the risk to mammals at the contaminated site based on whether said comparison exceeds the sperm parameter thresholds-for-effect.

As discussed at the interview, rodents are the "perfect real-world, worst-case receptors of exposure" because they may burrow in the contaminated soil, eat contaminated vegetation, drink contaminated water, and have continuous exposure to the soil. They typically do not migrate and many generations of rodents live in contaminated areas year after year. See specification at paragraph [0036]. Based upon the claimed Rodent Sperm Analysis (RSA), results can be extrapolated for other receptors, for example, regarding their contact with the ground and forage distances. See paragraph [0051].

The following art cited in the 1.131/1.132 Declaration was discussed:

- (1) *Toxicological Benchmarks for Wildlife: 1996 Revision*. ES/ER/TM-86/R3. Oak Ridge National Laboratory, Oak Ridge, TN, USA; and
- (2) *U.S. Environmental Protection Agency, Guidelines for Reproductive Toxicity Risk Assessment*, Office of Research and Development, Wash. D.C., USA (1996).

In particular, Applicant argued that that using rodents to assess toxicological data is known, as well as using rodent sperm data to estimate human health effects.